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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/151,885	09/11/1998	JAMES C. COSTIN	98-WL-1	8455

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EXAMINER

WHITE, EVERETT NMN

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 12/12/2001

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/151,885

Applicant(s)

COSTIN, JAMES C.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

1. The request filed on October 1, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/151,885 is acceptable and a CPA has been established. An action on the CPA follows.
2. Amendment C filed October 1, 2000 has been received and entered into the record.
3. Claims 7-12 are pending in the case. Claims 1-6 have been canceled.
4. All 35 U.S.C. statutes not cited in this Office action can be found cited in full in a previous Office action.

Specification

5. The abstract of the disclosure is objected to because the abstract does not coincide with the instantly claimed invention. The current abstract discloses 4,4-methylene bis (tetrahydro-1,2,4-thiadiazine-1,2-dioxide) being used to prevent and control the development of antibiotic drug resistance in bacterial and in the prevention of bacteria-to-bacteria transfer of genes capable of resisting antibiotics wherein the claims are directed to a method of reducing the adherence of microorganism to epithelial cells by treating the microorganisms or epithelial cells with 4,4'-methylene bis(perhydro-1,2,4-thiadiazine-1,1-dioxide). Correction is required. See MPEP § 608.01(b).
6. The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) Title of the Invention.
- (b) Cross-References to Related Applications.
- (c) Statement Regarding Federally Sponsored Research or Development.
- (d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).

- (e) Background of the Invention.
 - 1. Field of the Invention.
 - 2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) Brief Summary of the Invention.
- (g) Brief Description of the Several Views of the Drawing(s).
- (h) Detailed Description of the Invention.
- (I) Claim or Claims (commencing on a separate sheet).
- (j) Abstract of the Disclosure (commencing on a separate sheet).
- (k) Drawings.
- (l) Sequence Listing (see 37 CFR 1.821-1.825).

The abstract of the instant application is disclosed on page 1 and the specification starts on page 2.

Disclosure Objected To

7. The disclosure is objected to because of the following informalities: On page 2, lines 8 and 9 of the instant specification, the specification disclose the statement that “4,4'-methylene bis(tetrahydro-1,2,4 thiadiazine-1,2-dioxide) is known generically as Taurolidine”. However, there is evidence that this nomenclature for Taurolidine is incorrect. See the sheet attached to the end of this Office Action which suggests that the nomenclature for Taurolidine is 4,4'-methylene bis (perhydro-1,2,4 thiadiazine-1,1-dioxide)).

The compound “4,4'-methylene bis(tetrahydro-1,2,4 thiadiazine-1,2-dioxide” having the 1,2-dioxide group does not appear to be a stable compound. Applicants are requested to provide the structure for the compound 4,4'-methylene bis (tetrahydro-1,2,4 thiadiazine-1,2-dioxide so that the Examiner will have a better understanding of the claimed invention.

Appropriate correction is required.

35 U.S.C. 112, First Paragraph Rejection

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to

make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 7-12 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly added Claims 7-12 which are directed to a method for reducing the adherence of microorganisms to epithelial cells is not supported in the instant specification. Not only is the claimed invention not disclosed in the instant specification, but the term "epithelial cells" appears not to have been mentioned in the specification. Hence, Claims 7-12 set forth new matter which is improper under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 7 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Blenkarn (Surgical Res. Commun., Vol. 2, pp 149-155 (1987), already of record).

The Blenkarn reference discloses Taurolidine as having marked anti-adhesive properties with regard to the prevention of peritoneal adhesions and the adhesion of microorganisms to epithelial surfaces (see the abstract). The abstract discloses that detectable endotoxin concentrations subsequent to exposure of *Escherichia coli* to antibiotics were reduced up to 20-fold by Taurolidine which anticipates instant Claim 9 which discloses the microorganisms to be urine isolates of *Escherichia coli*.

12. Claims 7-9, 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorman et al (Journal of Pharmacy and Therapeutics, Vol. 12, pages 393-399 (1987)).

The Gorman et al reference disclose the examination of three antimicrobial agents that included Taurolidine for microbial anti-adherence activity. The Gorman et al reference disclosed that two adherence systems were investigated: an oral isolate of *Candida albicans* to human buccal epithelial cells and a urine isolate of *E. Coli* to human uroepithelial cells. Gorman et al reported that the agents exhibited significant anti-adherence activity (see abstract). This information disclosed in the Gorman et al reference anticipates the subject matter of Claims 7-9, 11 and 12 because each of the microorganisms, epithelial cells and anti-adhesive agent that is disclosed in the claims are discussed in the Gorman et al reference.

35 U.S.C. 103 Rejection

13. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gorman et al (Journal of Pharmacy and Therapeutics, Vol. 12, pages 393-399 (1987)) in view of Blenkharn (Surgical Res. Commun., Vol. 2, pp 149-155 (1987), already of record).

Applicant claims a method for reducing the adherence of microorganisms to epithelial cells which comprises treating the microorganisms or epithelial cells with 4,4'-methylene bis(perhydro-1,2,4 thiadiazine-1,1-dioxide).

The information disclosed in the Gorman et al and Blenkharn reference as discussed in the above rejection of the claims under 35 U.S.C. 102 is brought forth for the instant rejection. The instantly claimed invention differ from the Gorman et al and Blenkharn references by specifying *Staphylococcus saprophyticus* as the microorganism that is being treated with Taurolidine. However, the Blenkharn reference does disclose Taurolidine as having a uniquely broad spectrum of antibacterial and antifungal activity and it is noted in the prior art that many treatments used against *Staphylococcus aureus* (which is mentioned in the Blenkharn reference) are also effective against *Staphylococcus saprophyticus*. Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made, having before him the Gorman et al and Blenkharn references which discloses the use of Taurolidine to treat various microorganisms,

including *Staphylococcus aureus*, to also include in the treatment the microorganism *Staphylococcus saprophyticus*, in view of the recognition in the art, as evidenced by the Blenkarn reference, that Taurolidine has a uniquely broad spectrum of activity as an antibacterial and antifungal agent.

14. **Summary:** All the pending claims (7-12) are rejected.

Examiner's Telephone Number, Fax Number, and Other Information

15. For 24 hour access to patent application information 7 days per week, or for filing applications electronically, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to E. White whose telephone number is (703) 308-4621. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist, can be reached on (703) 308-1701. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

E. White

White

December 6, 2001



GARY GEIST
SUPERVISORY PATENT EXAMINER
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